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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/065,676 05/21/93 ILLUM

EPC 148
EXAMINER

KISHORE, G

ART UNIT PAPER NUMBER

6

LORUSSO & LOUD
440 COMMERCIAL ST.
BOSTON, MA 02109

15M1/0620

1502

DATE MAILED:

06/20/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 3-23-94 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-14 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-14 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Art Unit: 1502

Applicant's amendment and declaration dated March 23, 1994 are acknowledged.

Claims 3-4 and 6-8 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"derivatives" in claim 3 is still deemed to be indefinite. A case law regarding this term have already been cited by the examiner.

The indefiniteness of claim 6 is maintained. Applicant's own statements in the response indicate the confusion. Applicant states that heat stabilization normally denatures the microspheres, specially those made from proteinaceous material. If so, won't peptides such as insulin (claim 10) also be denatured. Applicant also states that heat treatment implements a structural change to the molecule which is not well defined. If it is not well defined how can it rule out crosslinking?

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5, 11 and 13 for reasons of record, remain rejected under 35 U.S.C. § 102(e) as being anticipated by Illum.

Applicant's arguments have been fully considered, but are not found to be persuasive. First of all, these are composition claims reciting an intended function, i.e., "for intranasal

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delivery". As written, the claim could imply that the drug has to be systemically active when administered. It is the examiner's position that sodium cromoglycate like any other biologically active compound when it enters the body. Secondly, applicant has not demonstrate the sodium cromoglycate does not penetrate the nasal tissue and enter the body to act systemically. Example 1 of Illum which shows that the particles were filtered through 5 micrometer filters is a clear indication of the particle size of less than 10 micrometers.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-14 for reasons of record, remain rejected under 35 U.S.C. § 103 as being unpatentable over Illum 1986.

Applicants' arguments that all of the microspheres disclosed in Illum are larger than 10 microns are not persuasive because the sizes referred to are swelled sizes and not unswelled. The instant claims do not recite swelled sizes of less than 10 microns.

Claims 7-12 and 14 for reasons of record, remain rejected under 35 U.S.C. § 103 as being unpatentable over Illum (4,847,091) or Illum (1986) in view of Hanson et al. or Salzman et al. to vice versa.

Applicant's arguments have been fully considered, but are found to be persuasive. Illum has already been discussed above.

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Applicant on page 11 of response states "microspheres of less than 10 microns provided significant improvements over larger sized microspheres". It is the examiner's position that significant improvement does not constitute unexpected results, but rather routine experimentation by an artisan of Illum's teachings (1986) on page 209, last four lines and finding that sizes of less than 10 microns are much better.

The declaration submitted by applicant has been considered, but is not found to be persuasive since it is not commensurate in scope of the claims.

The supplemental amendment filed on May 26, 1994 has been considered, but is not found to be persuasive. The reference submitted shows that cromoglycate is absorbed from gastrointestinal tract, but poorly. This in essence teaches that it is still systemically active, but not effectively.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to G.S. Kishore, PhD whose telephone number is (703) 308-2440.

Kishore:css
June 15, 1994
June 16, 1994

G.S. Kishore
PRIMARY EXAMINER
GROUP 1500